

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

November 25, 2003
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

CALL TO ORDER: A meeting of the Board of Pharmacy was called to order at 9:00 a.m.

PRESIDING: Mark A. Szalwinski, Chairman

MEMBERS PRESENT: Kimberly A. Anderson
Michael J. Ayotte
John O. Beckner
Willie Brown
Carthan F. Currin, Jr.
Michelle R. Easton
Bobby Ison
Leo H. Ross

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Ralph A. Orr, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Donna M. Lee, Administrative Assistant
Robert Nebiker, Director, Department of Health Professions

QUORUM: With nine members of the Board present, a quorum was established.

APPROVAL OF AGENDA Mr. Beckner moved, and the Board voted unanimously to approve the agenda as presented.

PUBLIC COMMENTS: No public comments were received at this time.

APPROVAL OF MINUTES: Mr. Szalwinski called for changes or corrections to the minutes of September 8, 2003. The minutes were amended on page 3 to add the date of June 8, 2004 as one of the upcoming Board meeting dates. Mr. Ayotte moved, and the Board voted unanimously, to approve the minutes as amended.

**BOARD RESPONSE TO
DPB ECONOMIC IMPACT
ANALYSIS:** Ms. Yeatts reviewed with the Board the proposed Agency response to the Economic Impact Analysis of the Department of Planning and Budget for amendments to 18 VAC 110-20-10. Mr. Brown moved, and the Board voted unanimously, to approve the proposed Agency response. (Attachment 1).

Mr. Oley arrived at 9:10 a.m.

Mr. Szalwinski amended the order of the agenda to consider the report from the Board of Health Professions before the presentation by Dr. McCance-Katz.

**REPORT FROM THE
BOARD OF HEALTH
PROFESSIONS:**

Ms. Easton informed the Board that the Board of Health Professions met on September 4, 2003 and October 22, 2003. The Chair and Vice-Chair were elected at the September 4, 2003 meeting. She also explained that during the discussion pertaining to the update on the implementation of the JLARC recommendations, that there were three recommendations put forth pertaining to the Board of Pharmacy as it relates to routine inspections every two years, re-establishment of a drug audit program and review of facility inspection programs.

Ms. Russell addressed the Board and explained that routine inspections are being done every two years. She explained that drug audits are conducted during routine inspections if deemed necessary by an inspector; and that target audits may be performed during an investigation or if there is a complaint. She further explained that routine drug audits were discontinued in the late 1980's because they were costly and did not prove to be effective or efficient in identifying diversion.

Mr. Beckner moved, and the Board voted unanimously, to advise the Board of Health Professions that it believes the current system of routine inspections and targeted audits is more efficient and a better use of resources than doing routine audits, and that the Board does not want a return to a routine audit system.

**PRESENTATION:
ELINORE MCCANCE-
KATZ, MD, PHD,
MEDICAL DIRECTOR
AND CHIEF OPERATING
OFFICER OF THE
HEALTH
PRACTITIONERS
INTERVENTION
PROGRAM (HPIP):**

Dr. McCance-Katz addressed the Board and provided information about the policies and procedures of HPIP and the maintenance pharmacotherapy program recommended by HPIP for certain healthcare practitioners in the program.

**BOARD RESPONSE TO
PETITION FOR
RULEMAKING – 1 YEAR
LIMIT ON REFILLS ON**

Ms. Russell informed the Board that this petition was originally discussed at the last Board meeting and was published for comment. The Board received no written comment. Rebecca Snead, Executive Director for the Virginia Pharmacists

SCHEDULE VI DRUGS:

Association, commented at the last meeting that changing the two-year limit for refills on a Schedule VI prescription to one year would be consistent with the policy of most third party payers, less confusing for patients, and would decrease pharmacist workload.

Mr. Beckner moved, and the Board voted unanimously, to approve the petition for rulemaking and to proceed with publication of a NOIRA.

**DISCUSSION OF
WHOLESALE-
DISTRIBUTOR
LICENSING AND
INSPECTION:**

Sammy Johnson, Deputy Director of Enforcement, addressed the Board regarding the current inspection plan of wholesale distributors that only requires an initial inspection at the time of application for licensure, with FDA conducting follow-up inspections. He further stated that with present concerns about counterfeiting of drugs, internet sales and importation from Canada and elsewhere, he would like to propose a modification to the current inspection plan to allow for routine inspections every two years for wholesale distributors.

Ms. Russell informed the Board that FDA was not aware that they had an agreement with the Board to conduct follow-up inspections and she was also told by FDA that they do not have legal authority to do inspections since they do not register wholesale distributors. She also stated that the state of Florida has experience in dealing with counterfeit drugs and would be willing to assist in providing training to our inspectors.

Mr. Ayotte moved, and the Board voted unanimously, to modify the current inspection plan to go to a two-year routine inspection program for wholesale distributors, within the next six months try to inspect all wholesale distributors to determine potential problems, send a mailing out to the non-resident wholesalers to determine licensing and inspection requirements, and to look at any needed legislative initiatives regarding wholesale distributors for the 2005 session.

**CONFIDENTIAL
CONSENT AGREEMENTS:**

The Board reviewed the recommendations of the ad hoc committee regarding the implementation of Confidential Consent Agreements.

Mr. Ayotte moved, and the Board voted unanimously, to approve the recommendations of the committee to include the revised Guidance Document 110-26 Inspection Violations-Suggested Sanctions and Guidance Document 110-19 Continuing Pharmacy Education Requirement Violations (Attachment 2)

**EXECUTIVE DIRECTOR'S
REPORT:**

- **RXPATROL**

Matthew E. Gainey, Director, Medical Liaisons for Purdue Pharma, provided information to the Board regarding the RxPatrol program, which collects theft/loss information from pharmacies.

- **TRAVEL
VOUCHERS/EDI**

Ms. Russell reviewed with the Board the guidelines for the submission of travel vouchers and provided a reference packet. She also explained the process of the Electronic Data Interchange.

Mr. Szalwinski amended the order of the agenda to discuss ex parte communications after new business.

- **ON LINE LICENSE
RENEWAL-ECI,
SURVEYS,
ADDRESS
CHANGES**

Ms. Russell informed the Board that on-line license renewal will be in effect starting with the 2004 renewal process. She explained that the Emergency Contact Information is collected for the Health Department to use in emergency situations to contact licensees.

- **POSTER SESSION
NABP ANNUAL
MEETING**

Ms. Russell informed the Board that the poster session will be held at the annual NABP meeting in Chicago. She encouraged the Board to think about topics that it could present at the annual meeting.

NEW BUSINESS:

Mr. Currin expressed his appreciation to Ms. Russell and Mr. Ayotte for their organization of the District II meeting that was held in Virginia.

**EX PARTE
COMMUNICATIONS:**

- **CLOSED SESSION:**

Mr. Oley moved, and the Board voted unanimously, to enter into closed session pursuant to Section 2.2-3711(A)(7) of the Code of Virginia for consultation with and the provision of legal advice by the Assistant Attorney General in the matter of ex parte communications. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Ralph Orr, Howard Casway, and Donna Lee attend the closed session because their presence is deemed necessary and will aid the Board in its deliberations.

- **RECONVENE:**

Mr. Oley moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

CONSENT ORDER:

- **CLOSED SESSION:** Mr. Oley moved, and the Board voted unanimously, to enter into closed session pursuant to Section 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a consent order. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, and Howard Casway attend the closed session because their presence is deemed necessary and will aid the Board in its deliberations.
- **RECONVENE:** Mr. Oley moved, and the Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

Mr. Brown moved, and the Board voted unanimously, to approve the consent order for Yvette King-Kennedy.

ADJOURN: With all business concluded, the meeting adjourned at 12:05 p.m.

Donna M. Lee
Administrative Assistant

Elizabeth Scott Russell
Executive Director

Mark A. Szalwinski, Board Chair

Date

**Agency Response to Economic Impact Analysis
Periodic Review
18 VAC 110-20: Regulations Governing the Practice of Pharmacy**

The Board of Pharmacy generally concurs with the analysis of the Department of Planning and Budget (DPB) for amendments to 18 VAC 110-20-10 et seq. as recommended during a periodic review of regulations.

However, there are several statements that need further explanation as follows:

Renewal and reinstatement

In the discussion of a required 160-hour internship for pharmacists who have a lapsed Virginia license and have not been actively practicing elsewhere, there is a statement that the pharmacist would likely be paid as a technician during the internship and therefore would lose as much as \$4,480. In reality, the current market for pharmacists is so competitive, it is more likely that the pharmacist would be paid a signing bonus and his full salary while he is serving the 160-hour internship. The pharmacy would ensure that he works along with another licensed pharmacist to oversee his work, but he would not be employed or paid as an intern or technician.

DPB further concludes that it is likely that the pharmacist who is serving the internship would likely learn about the changes in pharmacy law and regulation in recent years through instruction by the supervising pharmacist or PIC. The Board would take exception to such a presumption. First, the opportunities to learn state and federal laws do not always present themselves in a typical work environment; and second, it is incorrect to presume that all licensed pharmacists in Virginia are themselves current with changes in pharmacy law that occur on a regular basis. The only mechanism offering some assurance of knowledge of federal and state law is passage of the jurisprudence exam.

Practical experience

It is presumed that the problems described in the first paragraph of this section are directed to current regulation, while the second paragraph explains the benefit of the proposed regulation. The Board would prefer that there be a more clear distinction.

Labeling and packaging

In analyzing the proposed change to labeling requirements for hospitals and long term care facilities, DPB has concluded that it is not clear whether the cost savings of not adding the extra information exceeds the increased risk of accidental double doses. The Board would disagree that the change has the potential to increase the risk of double doses in any case. In both settings, there is a single provider or hospital pharmacy that is not going to dispense the same drug (generic and brand) to the same patient based on an order from a physician. The situations necessitating labeling with both names simply do not exist in those settings, so the current requirement places an unnecessary burden on those pharmacies that does not contribute to patient safety.

**CONFIDENTIAL CONSENT AGREEMENTS
RECOMMENDATIONS
October 23, 2003**

Ad Hoc Committee:
Michael J. Ayotte
Mark Szalwinski
Cathy M. Reiniers-Day
Elizabeth Scott Russell
Howard Casway
Gail Jaspen
Tammie D. Hall

Recommendations from the Committee that met on October 23, 2003 are incorporated in the attached revised *Guidance Document 110-26 Inspection Violations-Suggested Sanctions* and revised *Guidance Document 110-32 Continuing Pharmacy Education Requirement Violations*.

In addition, the Committee recommends:

- for matters where a pharmacist has practiced without a license for less than six months (December 31st through June 30th), a CCA should be offered;
- in following with the Agency's recommendation, once a Notice has been mailed, CCAs are no longer available for that particular matter.

GUIDANCE DOCUMENT NUMBER 110-32

Continuing Pharmacy Education Requirements Violations

Should a pharmacist not complete their continuing pharmacy education requirements and it is determined that this is the first time and that the conduct is not willful or intentional, the Board will offer a Confidential Consent Agreement (“CCA”) that will allow them to immediately obtain the missing hours. Original documentation of said missing hours shall be returned with the signed CCA.

Should it be determined that the conduct is willful or intentional, or it is the second or more occurrence for this violation, the Board will proceed with an informal conference and shall utilize the pharmacist’s previous continuing pharmacy education violations.

Sanctions, as previously outlined in the November 27, 2000 Minutes and resulting Guidance Document Number 19, would include a \$100 monetary penalty for each hour missing and \$300 for each fraudulent renewal certifying that the individual has complied with the continuing pharmacy education requirements, and that the missing hours must be completed and documentation submitted to the Board within 60 days of the date of entry of the Order.

Pharmacists may continue to request exemptions or extensions as provided in § 54.1-3314.1 of the Code of Virginia. Should an extension be granted, the pharmacist must obtain the hours within the time frame allotted by the Board.

Guidance Document 110-26

Inspection Violations-Suggested Sanctions

	Violation Cited	Charge ¹	1 st Time Cited	2 nd Time Cited
Security:				
1.	No lock on gate (or no gate) to prescription department	discretionary ²	Allow to fix	\$250
2.	Alarm dysfunctional	discretionary ²	Allow to fix	Informal Conference
3.	Not using alarm	discretionary ²	Informal Conference	Informal Conference
4.	Counter too low-not previously approved	discretionary ²	Allow to fix	Informal Conference
5.	Unauthorized persons have key/alarm code	discretionary ²	Has knowledge of: Informal Conference Other: Allow to fix	Informal Conference
6.	Key not in sealed envelope with signature	usually PIC	Allow to fix	Informal Conference
7.	Remodel the prescription department without submitting application or being inspected	usually owner	submit application and fee; fix anything not in compliance	
8.	Prescription drugs kept outside the prescription department	usually PIC	Allow to fix	
Records:				
9.	Failure to take or maintain biennial inventory	usually PIC	\$250 and notify owner	if same PIC, Informal Conference
10.	Failure to take change of PIC inventory, incoming or outgoing	discretionary ²	\$250	
11.	Theft of drugs not reported to the Board	discretionary ²	present to committee for review ³	
12.	Failure to maintain required invoices	discretionary ²	present to committee for review ³	
13.	Failure to maintain required records of distribution	discretionary ²	present to committee for review ³	
14.	Failure to produce requested records within the 48 hr. window	discretionary ²	present to committee for review ³	
Operations:				
15.	Failure to return PIC permit	former PIC	Allow to fix If an issue: present to committee for review ³	
16.	Have PIC in place but application is not submitted on time	discretionary ²	\$100	
17.	Exceeds allowed pharmacist to technician ratio	discretionary ²	present to committee for review ³ Beginning with February 26, 2004 Laws and Regulations: CCA	Informal Conference
18.	Dispenses prescription without pharmacist checking	pharmacist	Informal Conference	
19.	Operating w/out permit-after 14 day grace period (charge owner)	owner	Informal Conference	
20.	Failure to submit change in pharmacy hours to Board/public	discretionary ²	present to committee for review ³	

1. This column indicates the person usually charged for the violation, although this may change with circumstances showing responsibility by someone else.

2. Discretionary means that the decision to charge the pharmacist-in-charge, other pharmacist, and/or owner is at the discretion of the Board. The Board will have to review circumstances to charge the responsible party.

[For the above, the committee may recommend the use of a CCA when appropriate.]